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510(k) Summary

October 17, 2011

K102416
BD GeneOhm™ VanR Assay

Submitted by:

BD Diagnostics (GeneOhm Sciences, Inc.)
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Contact:

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Director, Regulatory Affairs
Molecular Diagnostics – MAX Platform

Name of Device:

Trade Name: BD GeneOhm™ VanR Assay

Common Name: Vancomycin-resistant Enterococci detection assay

Classification Name: System, Nucleic Acid Amplification Test, DNA, Vancomycin Resistant Bacteria, Direct Specimen

Predicate Device: Remel Bile Esculin Azide agar with 6 ug/mL vancomycin (BEAV) (K972359)

Device Description:

Intended Use:
The BD GeneOhm™ VanR Assay is a qualitative *in vitro* test for the rapid detection of vancomycin-resistance (*vanA* and *vanB*) genes directly from perianal or rectal swabs. The BD GeneOhm™ VanR Assay detects the presence of the *vanA* and *vanB* genes that can be associated with vancomycin-resistant enterococci (VRE). The assay is performed on an automated real-time PCR instrument with perianal or rectal swabs from individuals at risk for VRE colonization. The BD GeneOhm™ VanR Assay can be used as an aid to identify, prevent and control vancomycin-resistant colonization in healthcare settings. The BD GeneOhm™ VanR Assay is not intended to diagnose VRE infections nor to guide or monitor treatment for VRE infections. Concomitant cultures are necessary to recover organisms for epidemiological typing, susceptibility testing and for further confirmatory identification.

Test Description:
Following specimen lysis, the *vanA* and *vanB* genetic targets, if present, are amplified. Amplification of the Internal Control (IC), a DNA fragment of 294-bp including a 254-bp sequence not found in VRE, will also take place unless PCR inhibitory substances are present.

The amplified DNA targets are detected with molecular beacon probes, hairpin-forming single-stranded oligonucleotides labelled at one end with a quencher and at the other end with a fluorescent reporter dye (fluorophore). In the absence of target, the fluorescence is

quenched. In the presence of target, the hairpin structure opens upon beacon/target hybridization, resulting in emission of fluorescence. For the detection of the *vanA* amplicon, the molecular beacon probe contains the fluorophore FAM at the 5' end and the non-fluorescent quencher moiety DABCYL at the opposite 3' end of the oligonucleotide. For the detection of the *vanB* amplicon, the molecular beacon probe contains the fluorophore Texas Red at the 5' end and the quencher DABCYL at the 3' end. For the detection of the IC amplicon, the molecular beacon probe contains the fluorophore TET at the 5' end and the quencher DABCYL at the 3' end. Each beacon-target hybrid fluoresces at a wavelength characteristic of the fluorophore used in the particular molecular beacon probe. The amount of fluorescence at any given cycle, or following cycling, depends on the amount of specific amplicon present at that time. The SmartCycler® software simultaneously monitors the fluorescence emitted by each molecular beacon probe, interprets all data, and provides a final result at the end of the cycling program.

Substantial Equivalence:

The BD GeneOhm™ VanR Assay was originally cleared under premarket notification K061686 as the GeneOhm Sciences Canada, Inc. IDI-Van*R*™ Assay, for use with the rectal swab specimen collection method. This 510(k) notification was submitted for use with an additional specimen collection method, specifically, the perianal swab specimen collection method.

Additional clinical performance studies were performed to support the claims for either perianal or rectal specimen collection methods. The BD GeneOhm™ VanR Assay has been found to be substantially equivalent to the Remel Bile Esculin Azide agar with 6 ug/mL vancomycin (BEAV) (K972359) with phenotypic identification of *Enterococcus* colonies and confirmation of vancomycin resistance for the detection of vancomycin resistant Enterococcus, followed by genotypic characterization of the *vanA* or the *vanB* gene with alternative PCR.

Clinical Performance:

Performance characteristics of the BD GeneOhm™ VanR Assay were determined in a multi-site prospective investigational study. Five (5) medical centers participated in the study. To be enrolled in the study, specimens had to be from individuals for whom cultures were indicated and/or ordered, according to institutional policies.

The Reference Method consisted of direct culture complemented by enriched culture. Enriched culture analysis was completed for all specimens that were negative for VRE by direct culture. Direct culture was performed by inoculating specimens onto a primary isolation media containing Bile Esculin Azide agar supplemented with 6 µg/mL vancomycin (BEAV). Enriched culture was performed by inoculating 300 µL of sample buffer containing the specimen into BEA broth or BEAV broth (BEA broth supplemented with 6 µg/mL vancomycin). Confirmed enterococcal colonies were tested for vancomycin resistance. Genotypic characterization of confirmed vancomycin-resistant enterococcal isolates was performed using alternative PCR.

For the Reference Method, plates were directly inoculated with swab specimens followed by incubation at 35°C for 24 to 48 hours. Presumptive colonies of *Enterococcus* were subcultured to 5% sheep blood agar plates and incubated for 18-24 hours at 35°C. Colonies presumptive for the *Enterococcus* genus underwent the pyrrolidonyl arylamidase (PYR) test.

If the PYR test was positive, enterococcal species identification was performed using appropriate commercial tests. Vancomycin resistance was determined for confirmed enterococci using an MIC method. Confirmed VRE isolates underwent alternative PCR testing for genotypic characterization of *vanA* and *vanB* genes. An enrichment step in BEA broth or BEAV broth (BEA broth supplemented with vancomycin 6 □g/mL) was performed in cases where a negative result for vancomycin resistance was obtained with enterococci isolated from the BEAV plate or when no enterococci were isolated. For this purpose, the broth was inoculated with 300 µL of sample buffer containing the specimen, and incubated 24 to 48 hours at 35°C. Any broth culture that exhibited black growth was subcultured to a BEAV plate and incubated 24 to 48 hours at 35°C. Presumptive colonies of *Enterococcus* were subcultured to 5% sheep blood agar plates and incubated for 18-24 hours at 35°C. Confirmation of presumptive colonies and determination of vancomycin resistance was performed as described above. Confirmed VRE isolates underwent alternative PCR testing for genotypic characterization of *vanA* and *vanB* genes.

A *vanA*- and/or *vanB*-containing VRE positive specimen was defined as a specimen with vancomycin-resistant enterococci from culture with *vanA* and/or *vanB* genes identified by alternative PCR; a VanR-positive specimen was defined as a VRE having *vanA*, *vanB* or both. A negative specimen was defined as a specimen negative for vancomycin-resistant enterococci by both direct and enriched culture methods.

A total of 2156 specimens were tested using Direct/Enriched culture with alternative PCR and the BD GeneOhm VanR™ Assay, producing 2150 reportable results. Tables 1A and 1B show the final results (1316 perianal and 834 rectal specimens) of the BD GeneOhm VanR™ Assay in comparison to Direct/Enriched culture with alternative PCR. Two hundred and twenty-two (222) specimens (123 perianal and 99 rectal) were culture negative but positive for *vanB* only by the BD GeneOhm VanR™ PCR and may represent detection of the *vanB* gene in non-enterococcal organisms. Further investigation for non-enterococcal organisms that might contain the *vanB* gene was not performed.

In comparison to Direct/Enriched culture with alternative PCR, the BD GeneOhm™ VanR Assay identified 81.3% to 100% of the VanR-positive specimens and 72.7% to 93.1% of the negative specimens (Table 3A). The BD GeneOhm™ VanR Assay identified 92.9% and 93.1% of the perianal and rectal positive specimens, respectively, and identified 86.0% and 82.2% of the perianal and rectal negative specimens, respectively (Tables 2A and 2B).

Tables 1A-B. Results Obtained with the BD GeneOhm™ VanR Assay in Comparison to Direct/Enriched Culture with Alternative PCR

Table 1A. Perianal Specimens

		Direct/Enriched Culture + Alternative PCR				
		VRE with *vanA* Genotype	VRE with *vanB* Genotype	VRE with *vanA* and *vanB* Genotype	Negative	Total
BD GeneOhm™VanR Results	*vanA*	106	0	0	35	141
	vanA and *vanB*	28	0	0	5	33
	vanB	7	3	0	123	133
	Negative	11	0	0	998	1009
	Total	152	3	0	1161	1316

Table 1B. Rectal Specimens

		Direct/Enriched Culture + Alternative PCR				
		VRE with *vanA* Genotype	VRE with *vanB* Genotype	VRE with *vanA* and *vanB* Genotype	Negative	Total
BD GeneOhm™VanR Results	*vanA*	75	0	0	20	95
	vanA and *vanB*	32	2	1	6	41
	vanB	8	4	0	99	111
	Negative	9	0	0	578	587
	Total	124	6	1	703	834

Tables 2A-B. Clinical Performance Obtained with the BD GeneOhm™ VanR Assay by Specimen Type in Comparison to Direct/Enriched Culture with Alternative PCR

Table 2A. Perianal Specimens

	Sensitivity (95% CI[1])	Specificity (95% CI[1])	VRE Prevalence	PPV (95% CI[1])	NPV (95% CI[1])
vanA	88.2% (134/152) (81.9% - 92.8%)	96.6% (1124/1164) (95.3% - 97.5%)	11.1% (152/1372)	77.0% (134/174) (70.0% - 83.0%)	98.4% (1124/1142) (97.5% - 99.1%)
vanB	100.0% (3/3) (29.2% - 100.0%)	87.6% (1150/1313) (85.7% - 89.3%)	0.2% (3/1372)	1.8% (3/166) (0.4% - 5.2%)	100.0% (1150/1150) (99.7% - 100.0%))
VanR	92.9% (144/155) (87.7% - 96.4%)	86.0% (998/1161) (83.8% - 87.9%)	11.3% (155/1372)	46.9% (144/307) (41.2% - 52.7%)	98.9% (998/1009) (98.1% - 99.5%)

[1] Binomial 95% exact confidence intervals.

Table 2B. Rectal Specimens

	Sensitivity (95% CI[1])	Specificity (95% CI[1])	VRE Prevalence	PPV (95% CI[1])	NPV (95% CI[1])
vanA	86.4% (108/125) (79.1% - 91.9%)	96.1% (681/709) (94.3% - 97.4%)	15.4% (133/863)	79.4% (108/136) (71.6% - 85.9%)	97.6% (681/698) (96.1% - 98.6%)
vanB	100.0% (7/7) (59.0% - 100.0%)	82.5% (682/827) (79.7% - 85.0%)	1.0% (9/863)	4.6% (7/152) (1.9% - 9.3%)	100.0% (682/682) (99.5% - 100.0%)
VanR	93.1% (122/131) (87.4% - 96.8%)	82.2% (578/703) (79.2% - 85.0%)	16.3% (141/863)	49.4% (122/247) (43.0% - 55.8%)	98.5% (578/587) (97.1% - 99.3%)

[1] Binomial 95% exact confidence intervals.

Tables 3A-C. Clinical Performance Obtained with the BD GeneOhm™ VanR Assay by site in Comparison to Direct/Enriched Culture with Alternative PCR

Table 3A. VanR

Investigational Site	Collection Method	VRE Prevalence	Sensitivity (95% CI[1])	Specificity (95% CI[1])
Site 1	Perianal	8.6% (16/185)	81.3% (13/16) (54.4% - 96.0%)	93.1% (134/144) (87.6% - 96.6%)
	Rectal	17.0% (19/112)	100.0% (17/17) (80.5% - 100.0%)	75.3% (67/89) (65.0% - 83.8%)
Site 2	Perianal	15.6% (60/385)	100.0% (54/54) (93.4% - 100.0%)	81.0% (217/268) (75.8% - 85.5%)
Site 3	Rectal	23.4% (79/338)	94.3% (66/70) (86.0% - 98.4%)	72.7% (168/231) (66.5% - 78.4%)
Site 4	Perianal	9.5% (75/789)	90.1% (73/81) (81.5% - 95.6%)	86.5% (640/740) (83.8% - 88.9%)
	Rectal	10.1% (8/79)	88.9% (8/9) (51.8% - 99.7%)	83.3% (60/72) (72.7% - 91.1%)
Site 5	Perianal	30.8% (4/13)	100.0% (4/4) (39.8% - 100.0%)	77.8% (7/9) (40.0% - 97.2%)
	Rectal	10.5% (35/334)	88.6% (31/35) (73.3% - 96.8%)	91.0% (283/311) (87.3% - 93.9%)

[1] Binomial 95% exact confidence intervals.

Table 3B. *vanA*

Investigational Site	Collection Method	VRE Prevalence	Sensitivity (95% CI[1])	Specificity (95% CI[1])
Site 1	Perianal	8.6% (16/185)	81.3% (13/16) (54.4% - 96.0%)	98.6% (142/144) (95.1% - 99.8%)
	Rectal	17.0% (19/112)	94.1% (16/17) (71.3% - 99.9%)	97.8% (87/89) (92.1% - 99.7%)
Site 2	Perianal	15.3% (59/385)	96.2% (51/53) (87.0% - 99.5%)	91.4% (246/269) (87.4% - 94.5%)
Site 3	Rectal	21.0% (71/338)	84.4% (54/64) (73.1% - 92.2%)	93.2% (221/237) (89.3% - 96.1%)
Site 4	Perianal	9.3% (73/789)	84.8% (67/79) (75.0% - 91.9%)	98.1% (728/742) (96.9% - 99.0%)
	Rectal	10.1% (8/79)	88.9% (8/9) (51.8% - 99.7%)	100.0% (72/72) (95.0% - 100.0%)
Site 5	Perianal	30.8% (4/13)	75.0% (3/4) (19.4% - 99.4%)	88.9% (8/9) (51.8% - 99.7%)
	Rectal	10.5% (35/334)	85.7% (30/35) (69.7% - 95.2%)	96.8% (301/311) (94.2% - 98.4%)

[1] Binomial 95% exact confidence intervals.

Table 3C. *vanB*

Investigational Site	Collection Method	VRE Prevalence	Sensitivity (95% CI[1])	Specificity (95% CI[1])
Site 1	Perianal	0.0% (0/185)	No data for sensitivity rate calculation	93.8% (150/160) (88.8% - 97.0%)
	Rectal	0.0% (0/112)	No data for sensitivity rate calculation	75.5% (80/106) (66.2% - 83.3%)
Site 2	Perianal	0.3% (1/385)	100.0% (1/1) (2.5% - 100.0%)	87.5% (281/321) (83.4% - 90.9%)
Site 3	Rectal	2.7% (9/338)	100.0% (7/7) (59.0% - 100.0%)	73.5% (216/294) (68.0% - 78.4%)
Site 4	Perianal	0.3% (2/789)	100.0% (2/2) (15.8% - 100.0%)	86.7% (710/819) (84.2% - 88.9%)
	Rectal	0.0% (0/79)	No data for sensitivity rate calculation	81.5% (66/81) (71.3% - 89.2%)
Site 5	Perianal	0.0% (0/13)	No data for sensitivity rate calculation	69.2% (9/13) (38.6% - 90.9%)
	Rectal	0.0% (0/334)	No data for sensitivity rate calculation	92.5% (320/346) (89.2% - 95.0%)

[1] Binomial 95% exact confidence intervals.

A total of 2152 specimens were tested using Direct Culture with alternative PCR and the BD GeneOhm VanR™ Assay, producing 2146 reportable results. Tables 4A and 4B show the final results (1314 perianal and 832 rectal specimens) of the BD GeneOhm VanR™ Assay in comparison to Direct Culture with alternative PCR. Two hundred and thirty-one (231) specimens (129 perianal and 102 rectal) were culture negative but positive for *vanB* only by the BD GeneOhm VanR™ PCR and may represent detection of the *vanB* gene in non-enterococcal organisms. Further investigation for non-enterococcal organisms that might contain the *vanB* gene was not performed.

In comparison to Direct Culture with alternative PCR, the BD GeneOhm™ VanR Assay identified 86.7% to 100% of the VanR-positive specimens and 71.0% to 93.1% of the negative specimens (Table 6A). The BD GeneOhm™ VanR Assay identified 95.0% and 95.5% of the perianal and rectal positive specimens, respectively, and identified 83.9% and 81.0% of the perianal and rectal negative specimens, respectively (Tables 5A and 5B).

Tables 4A-B. Results Obtained with the BD GeneOhm™ VanR Assay in Comparison to Direct Culture with Alternative PCR

Table 4A. Perianal Specimens

		Direct Culture + Alternative PCR				
		VRE with *vanA* Genotype	VRE with *vanB* Genotype	VRE with *vanA* and *vanB* Genotype	Negative	Total
BD GeneOhm™VanR Results	*vanA*	82	0	0	57	139
	vanA and *vanB*	27	0	0	6	33
	vanB	3	1	0	129	133
	Negative	6	0	0	1003	1009
	Total	118	1	0	1195	1314

Table 4B. Rectal Specimens

		Direct Culture + Alternative PCR				
		VRE with *vanA* Genotype	VRE with *vanB* Genotype	VRE with *vanA* and *vanB* Genotype	Negative	Total
BD GeneOhm™VanR Results	*vanA*	65	0	0	28	93
	vanA and *vanB*	31	2	1	7	41
	vanB	4	4	0	102	110
	Negative	5	0	0	583	588
	Total	105	6	1	720	832

Tables 5A-B. Clinical Performance Obtained with the BD GeneOhm™ VanR Assay by Specimen Type in Comparison to Direct Culture with Alternative PCR

Table 5A. Perianal Specimens

	Positive Percent Agreement (95% CI[1])	Negative Percent Agreement (95% CI[1])
vanA	92.4% (109/118) (86.0%-96.5%)	94.7% (1133/1196) (93.3%-95.9%)
vanB	100.0% (1/1) (2.5%-100.0%)	87.4% (1148/1313) (85.5%-89.2%)
VanR	95.0% (113/119) (89.3%-98.1%)	83.9% (1003/1195) (81.7%-86.0%)

[1] Binomial 95% exact confidence intervals.

Table 5B. Rectal Specimens

	Positive Percent Agreement (95% CI[1])	Negative Percent Agreement (95% CI[1])
vanA	91.5% (97/106) (84.5%-96.0%)	94.9% (689/726) (93.0%-96.4%)
vanB	100.0% (7/7) (59.0%-100.0%)	82.5% (681/825) (79.8%-85.1%)
VanR	95.5% (107/112) (89.9%-98.5%)	81.0% (583/720) (77.9%-83.8%)

[1] Binomial 95% exact confidence intervals.

Tables 6A-C. Clinical Performance Obtained with the BD GeneOhm™ VanR Assay by Site in Comparison to Direct Culture with Alternative PCR

Table 6A. VanR

Investigational Site	Collection Method	Positive Percent Agreement (95% CI[1])	Negative Percent Agreement (95% CI[1])
Site 1	Perianal	86.7% (13/15) (59.5% - 98.3%)	93.1% (135/145) (87.7% - 96.6%)
	Rectal	100.0% (16/16) (79.4% - 100.0%)	74.4% (67/90) (64.2% - 83.1%)
Site 2	Perianal	100.0% (35/35) (90.0% - 100.0%)	75.6% (217/287) (70.2% - 80.5%)
Site 3	Rectal	95.2% (59/62) (86.5% - 99.0%)	71.0% (169/238) (64.8% - 76.7%)
Site 4	Perianal	93.8% (61/65) (85.0% - 98.3%)	85.4% (644/754) (82.7% - 87.9%)
	Rectal	100.0% (6/6) (51.1% - 100.0%)	81.3% (61/75) (70.7% - 89.4%)
Site 5	Perianal	100.0% (4/4) (39.8% - 100.0%)	77.8% (7/9) (40.0% - 97.2%)
	Rectal	92.9% (26/28) (76.5% - 99.1%)	90.2% (286/317) (86.4% - 93.3%)

[1] Binomial 95% exact confidence intervals.

Table 6B. *vanA*

Investigational Site	Collection Method	Positive Percent Agreement (95% CI[1])	Negative Percent Agreement (95% CI[1])
Site 1	Perianal	86.7% (13/15) (59.5%-98.3%)	98.6% (143/145) (95.1% - 99.8%)
	Rectal	100.0% (16/16) (79.4% - 100.0%)	97.8% (88/90) (92.2% - 99.7%)
Site 2	Perianal	97.1% (33/34) (84.7% - 99.9%)	85.8% (247/288) (81.2% - 89.6%)
Site 3	Rectal	87.5% (49/56) (75.9% - 94.8%)	91.4% (223/244) (87.1% - 94.6%)
Site 4	Perianal	92.3% (60/65) (83.0% - 97.5%)	97.5% (735/754) (96.1% - 98.5%)
	Rectal	100.0% (6/6) (54.1% - 100.0%)	97.3% (73/75) (90.7% - 99.7%)
Site 5	Perianal	75.0% (3/4) (19.4% - 99.4%)	88.9% (8/9) (51.8% - 99.7%)
	Rectal	92.9% (26/28) (76.5 - 99.1%)	96.2% (305/317) (93.5% - 98.0%)

[1] Binomial 95% exact confidence intervals.

Table 6C. *vanB*

Investigational Site	Collection Method	Positive Percent Agreement (95% CI[1])	Negative Percent Agreement (95% CI[1])
Site 1	Perianal	No data for sensitivity rate calculation	93.8% (150/160) (88.8% - 97.0%)
	Rectal	No data for sensitivity rate calculation	75.5% (80/106) (66.2% - 83.3%)
Site 2	Perianal	100.0% (1/1) (2.5% - 100.0%)	87.5% (281/321) (83.4% - 90.9%)
Site 3	Rectal	100.0% (7/7) (59.0% - 100.0%)	73.7% (216/293) (68.3% - 78.7%)
Site 4	Perianal	No data for sensitivity rate calculation	86.4% (708/819) (83.9% - 88.7%)
	Rectal	No data for sensitivity rate calculation	81.5% (66/81) (71.3% - 89.2%)
Site 5	Perianal	No data for sensitivity rate calculation	69.2% (9/13) (38.6% - 90.9%)
	Rectal	No data for sensitivity rate calculation	92.5% (319/345) (89.2% - 95.0%)

[1] Binomial 95% exact confidence intervals.

Twenty-three (23) specimens gave an initial Unresolved result (i.e. failure of the internal control), giving a rate of 1.1%. Upon retest, 17 of these specimens gave a reportable result whereas only 6 specimens remained Unresolved, producing a final Unresolved rate of 0.3% (Table 7).

Table 7. Initial and Repeat Unresolved Rates of the BD GeneOhm™ VanR Assay

Investigational Site	Initial unresolved rate (95% CI[1])	Unresolved rate after repeat (95% CI[1])
Site 1	0.0% (0/266) (0.0% - 1.4%)	0.0% (0/266) (0.0% - 1.4%)
Site 2	1.9% (6/322) (0.7% - 4.0%)	0.0% (0/322) (0.0% - 1.1%)
Site 3	1.7% (5/301) (0.5% - 3.8%)	0.0% (0/301) (0.0% - 1.2%)
Site 4	1.1% (10/908) (0.5% - 2.0%)	0.7% (6/908) (0.2% - 1.4%)
Site 5	0.6% (2/359) (0.1% - 2.0%)	0.0% (0/359) (0.0% - 1.0%)
Overall study	1.1% (23/2156) (0.7% - 1.6%)	0.3% (6/2156) (0.1% - 0.6%)

[1] Binomial 95% exact confidence intervals.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

BD Diagnostics (GeneOhm Sciences, Inc.)
c/o Mr. Raymond J. Boulé
Director, Regulatory Affairs
7 Loveton Circle, Mail Code 614
Sparks, MD 21152

OCT 2 0 2011

Re: K102416

Trade/Device Name: BD GeneOhm™ VanR Assay
Regulation Number: 21 CFR§866.1640
Regulation Name: Antimicrobial susceptibility test powder
Regulatory Class: Class II
Product Code: NIJ
Dated: October 18, 2011
Received: October 18, 2011

Dear Mr. Boulé:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration

and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K102416

Device Name: BD GeneOhm™ VanR Assay

Indications For Use:

Intended Use

The BD GeneOhm™ VanR Assay is a qualitative *in vitro* test for the rapid detection of vancomycin-resistance (*vanA* and *vanB*) genes directly from perianal or rectal swabs. The BD GeneOhm™ VanR Assay detects the presence of the *vanA* and *vanB* genes that can be associated with vancomycin-resistant enterococci (VRE). The assay is performed on an automated real-time PCR instrument with perianal or rectal swabs from individuals at risk for VRE colonization. The BD GeneOhm™ VanR Assay can be used as an aid to identify, prevent and control vancomycin-resistant colonization in healthcare settings. The BD GeneOhm™ VanR Assay is not intended to diagnose VRE infections nor to guide or monitor treatment for VRE infections. Concomitant cultures are necessary to recover organisms for epidemiological typing, susceptibility testing and for further confirmatory identification.

Prescription Use ____XXX_____ OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices Evaluation and Safety (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K102416